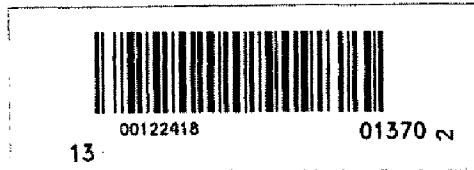


לשימוש הלשכה
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מספר: Number	122418/2
תאריך: Date	02.12.1997
הוקדם/נדחה Ante/Post-dated	



חוק הפטנטים, התשכ"ז-1967
PATENTS LAW, 5727-1967
בקשה לפטנט
Application for Patent

אני, (שם המבקש, מענו - ולגבי גוף מאוגד - מקום התאגדותו)
I (Name and address of applicant, and, in case of a body corporate, place of incorporation)

וייס-מד בע"מ, ת.ד. 3582, קיסריה 38900

WAIS-MED LTD., P.O. Box 3582, Caesarea 38900

ששמה הוא:
Owner, by virtue of assignment

בעל אמצאה מכח העברת בעלות
of an invention, the title of which is:

(בעברית)
מקבע חיצוני לעצם החזה
(Hebrew)

STERNAL EXTERNAL FIXATOR

(באנגלית)
(English)

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן לי עליה פטנט.

* בקשת חלוקה - Application for Division		* בקשת פטנט מוסף - Application for Patent of Addition		* דרישת דין קדימה Priority Claim		
מבקשת פטנט from Application		לבקשה/לפטנט to Patent/Apl.		מספר/סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
No. _____ מס' _____ dated _____ מיום _____		No. _____ מס' _____ dated _____ מיום _____				
* יפוי כח: כללי/מומחה - רצוף כוח / P.O.A.: general / attached / חוגש בענין _____ Has been filed in case _____						
המען למסירת הודעות ומסמכים בישראל Address for Service in Israel גלוקסמן-לוי, עורכי פטנטים - (9720) ת.ד. 6202, חיפה 31061 GLUCKSMAN-LOWY, P.O.B. 6202, Haifa						
חתימת המבקש Signature of Applicant A. LOWY 				רשם הפטנטים - הספרייה 23-12-2001 Publication date: _____		
				היום 23 בחודש יולי שנת 2001 This 23 of July 2001		
				לשימוש הלשכה For Office Use		

"STERNAL EXTERNAL FIXATOR"

"מקבע חיצוני לעצם החזה"

STERNAL EXTERNAL FIXATOR

The invention relates to a medical device in use with open heart, vascular and thoracic surgery. It relates particularly to accelerate and improve the healing process of the sternum by fixing the osteotomized fragments of the sternum in their correct position to promote healing by exerting the necessary immobilization and pressure on the sternal fragments.

BACKGROUND OF THE INVENTION.

In order to perform cardio-thoracic operations it is necessary to expose the target organs by sawing the breastbone or sternum into two halves along its midline. This operation permits lateral retraction and separation of the fragments together with the attached ribs to both sides. After completion of the main operation the chest is closed by anatomic repositioning of the two sternal halves and approximating them to promote rapid healing.

The sternum is a flat bone consisting of about 90% soft spongy material with a minimal cortical bone frame. It possesses a particular vascularization which is usually severely damaged by the central osteotomy and which should be repaired during the healing process. The conventional

closure technique comprises circular wiring (cerclage) which has the disadvantage of strangulating the osteotomized bone and may lead to more vascular damage and to severe complications such as bone necrosis, deep infection, non-union with following pain, poor ventilation and subsequent increased morbidity and mortality.

It is, therefore, the object of the present invention to provide a closure device for the osteotomized sternum which does not strangulate the bone and will avoid vascular damage of the sternum and promote rapid healing.

It is another object to provide closure means that provide semi-rigid fixation of the thoracic cage as required for thorough healing of the sternal bone.

It is a further object to provide closure means permitting ready and simple application by the medical personnel; likewise permitting ready and easy removal of the external parts of the closure device, while leaving only small parts of bio-reabsorbable or of other inert materials in the chest.

And it is a final object to provide components of this closure device made of materials that can remain in the

chest during the healing period or during the entire life of the patient without damage to him or her.

SUMMARY OF THE INVENTION

The closure device for an osteotomized sternum, according to the present invention, is in the form of one or more external fixators. Each fixator comprises internal components which are attached to the outer edges of the two sternal fragments and are configured to remain there after healing of the bone, and external components serving to correctly positioning the two sternum parts and to produce the necessary pressure to promote healing before they are removed.

The fixator includes essentially internal components in the shape of two pairs of disks, each pair mounted on a screw-threaded shaft and movable along the shaft by rotating each disk. The external components include a toothed bar and two blocks movable along the bar and adapted to be secured at the required distance from each other. Each block is provided with a perforation perpendicular to the axis of the bar, adapted to hold one of the two shafts and to keep it in position by means of a screw pressing onto the shaft. Each block is provided with one or two pawls engaging with a tooth of the bar, thus

serving as a ratchet and securing the block in its required position.

As an alternative the bar is smooth and each block is secured in its position by means of a screw impinging on the bar.

The disks are manufactured of a bio-reabsorbable or other inert material and are preferably perforated by a number of holes enhancing their incorporation in the scar tissue surrounding the sternum.

After closing of the thorax the sternum is held in healing position and at the suitable pressure upon the two sternal fragments by two or more of the above described fixators. One set each of shaft and its two disks is placed into an intercostal space at the outer edge of the sternum at the back and the front thereof. The disks are rotated so as to grip the bone firmly between the anterior and posterior surface of the sternal edges. Tissue and skin are pulled over the sternum and sutured, and the shafts are made to penetrate them to the outside. The two shafts of each fixator are now inserted into the perforations in the two blocks while these are either mounted on the toothed bar at the suitable distance, or the bar is threaded into the blocks. The two shafts are now secured in the blocks by

closing the screws upon them and the blocks are shifted towards each other to obtain the required pressure between the two sternal fragments. The external components of the fixators are covered by bandages which are removed after complete healing, permitting removal of the bar and blocks as well as the shafts which are screwed out of the disks, while the latter remain attached to the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an isometric view of an assembled fixator,
Figure 2 is a side view of a part of the fixator of Figure 1, showing the pawls of the ratchet,
Figure 3 is a part view of a fixator having a smooth bar,
Figure 4 illustrates a side view and part section of a block of the fixator of Figure 3,
Figure 5 illustrates a sternum with three fixatores attached, and
Figure 6 is a section along line 6-6 of Figure 5.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figures 1 and 2 a complete fixator comprises four disks 1 configured to remain in the body after healing and external components to be removed from the patient's body after healing. Each disk 1 is perforated by

a number of holes 2 and features a hub 3 with internal screwthread. Two disks each are mounted on one of two screwthreaded shafts 4 and are adapted to be shifted along each shaft so as to grip the edge of the sternum from back and front. The two shafts penetrate through body tissue and skin to the front of the chest and are connected and fixed to a horizontal bar 5 by means of two blocks 6. The bar is toothed by saw teeth 7 and 7' at opposite ends which are directed in opposite direction to serve as ratchets with pawls 8 (Fig.2). The two blocks are horizontally perforated by bores 10 and hold one shaft 4 which is secured in correct position by a screw 9 movable in vertical screwthread in each block.

A modified bar and mode of fastening the shafts is illustrated in Figures 3 and 4. Herein the bar 15 is smooth, and the two blocks 16 can be easily slid along the bar. The shafts 4 are held in bores 10 which adjoin the bar 15 (Fig.4) permitting clamping of both block and shaft by means of a screw 11. After shifting the blocks along the bar so as to maintain the correct pressure on the sternum fragments, the screws 11 secure both the blocks and the shafts in the required position.

Figures 5 and 6 illustrate a sternum A cut into two fragments by a cut B. Three fixators are attached to the

outer edges at different height and hold the fragments in correct anatomical position as well as pressing them onto each other at a desired pressure.

It will be understood that the disks and the screw-threaded shafts can be adapted to different ages and sizes of the patient by being of larger or smaller diameter and/or length. On the other hand there is much scope for change of the external components such as the bar and the blocks. The bar, for instance, may be in the shape of a cylindrical bar provided with left and right thread at the respective ends, whereby the two blocks are provided with corresponding internal screwthread. The blocks may be cylindrical or otherwise shaped, as long as they are adapted to move along the bar and to secure the shafts.

SURGICAL TECHNIQUE FOR STERNAL AND SKIN CLOSURE

1. Introduce the disk couple from inside to outside in several intercostal spaces, just at bilateral external edge of the sternum. The threaded shaft 4 must penetrate through the parietal pleura, intercostal muscle and fascia.
2. Screw a couple disks gripping the ribs and sternum in 2 or 3 intercostal spaces.

3. Suture the fascia with number 2 rearsorbable polyglycolic sutures for approximation of both sternum fragmnts.
4. Perforate the skin with shafts 4 and suture the skin with a standard technique.
5. Introduce the shafts into the blocks and with gentle manual compression towards the midline approximate the shafts from both opposite sides with the ratchet.
6. Protect the shaft skin junction with polydine or antibiotic ointment for prevention of infection. A suitable dressing or a special plastic cup covering the external fixator parts is recommended for protection of the wound and the device.
7. After bone healing is completed (6 to 10 weeks) remove the shafts and blocks unscrewing the shafts from the disks. The remaining disks will be reabsorbed or will remain in situ.

C L A I M S :-

1. An external fixator for an osteotomized sternum in use in open heart, vascular and thoracic surgery, configured to hold the sternal fragments in correct position and to urge them onto each other at a predesignated pressure for improved and rapid healing, the fixator comprising,

two pairs of disks of a bio-reabsorbable or an inert material such as Titanium or silicone, each disk being provided with a central inner screwthread, said disks being configured to remain in the chest after completed healing,

two shafts with outer screwthread corresponding to the screwthread in said disks, each shaft carrying two of said disks to be urged onto the anterior and posterior surfaces at the outer edges of said sternal fragments, and each said shaft extending to the outside through tissue and skin of the chest,

a bar of a length greater than the width of said sternum and two blocks slidably movable along said bar and to be firmly secured in a predesignated position on said bar, each said block being provided with a bore for receiving the end of one of said shafts and with means for clamping said shaft in said block.

2. The fixator of Claim 1, wherein each said disk is provided with several perforations.

3. The fixator of Claim 1, wherein said bar is of rectangular cross section.

4. The fixator of Claim 3, wherein at least one surface of said bar is saw-teethed in opposite direction at opposite ends, and wherein said blocks feature pawls in contact with said teeth to act as ratchets to prevent said blocks from being moved towards the ends of said bar after having been shifted towards each other.

5. The fixator of Claim 4, wherein each block is perforated by a first bore corresponding to the cross section of said bar and with a second bore corresponding to the size of said shaft at right angles to the direction of said first bore.


6. The fixator of Claim 5, wherein each said shaft is held in position in said second bore in said block by a screw movable in a threaded bore in said block.

7. The fixator of Claim 5, wherein said first bore is adjacent said second bore in perpendicular alignment, and wherein one screw is adapted to be pressed onto said shaft and to hold said shaft and block in position by pressure exerted by said shaft onto said bar.

8. The fixator of Claim 5, wherein said first bore is adjacent said second bore in perpendicular alignment, and wherein one screw is adapted to be pressed onto said bar and to hold said block and said shaft in position by pressure exerted by said bar onto said shaft.

9. The fixator as defined in any of Claims 1 through 8, and substantially as herein before described with reference to the accompanying drawings.

For the Applicant,



E.A. Glucksman

Patent Attoreny

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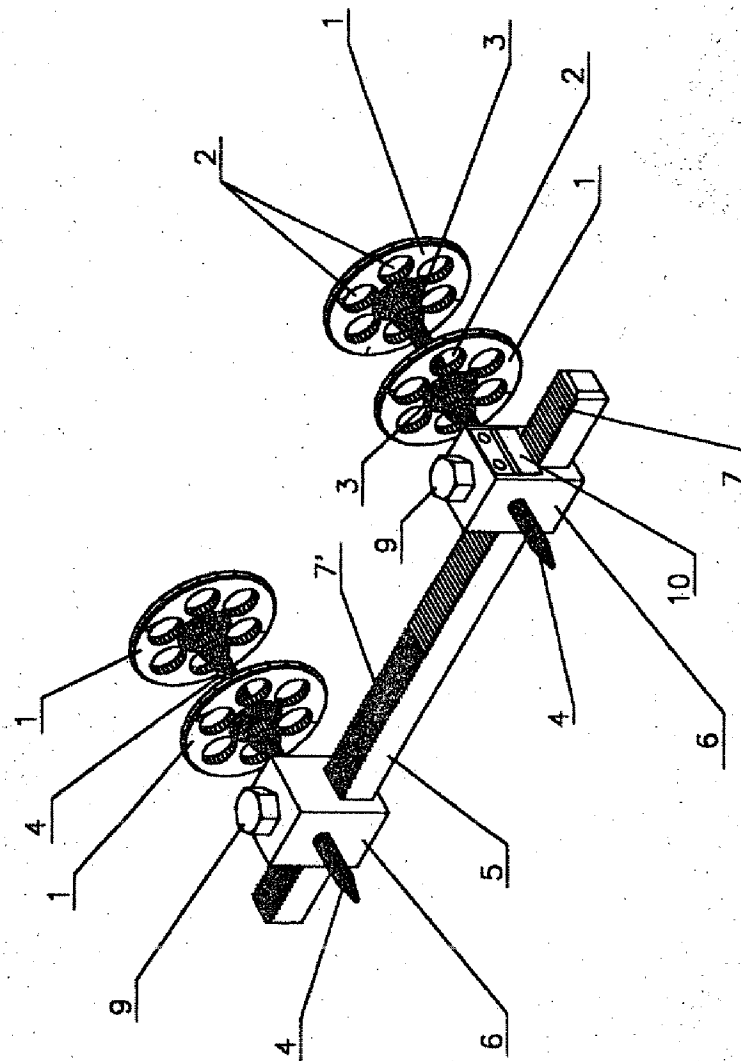


FIG. 1

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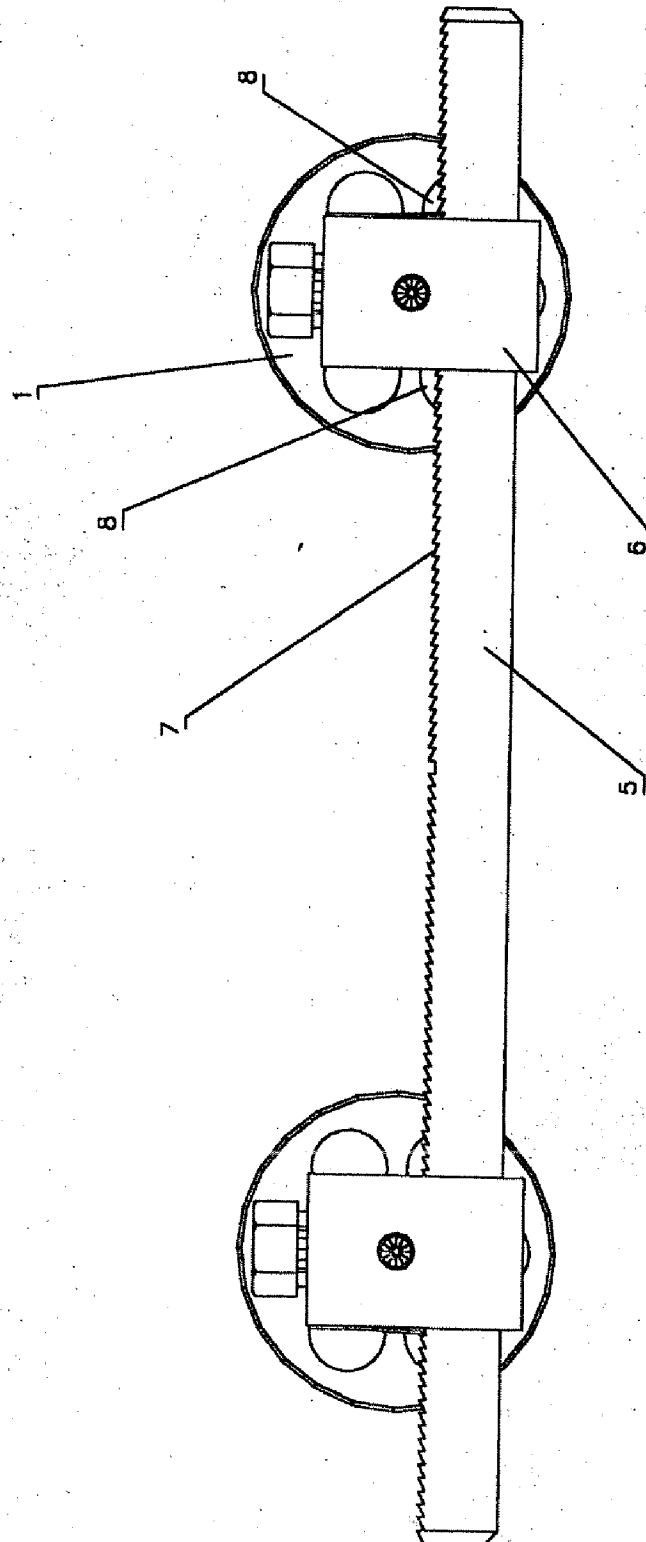


FIG. 2

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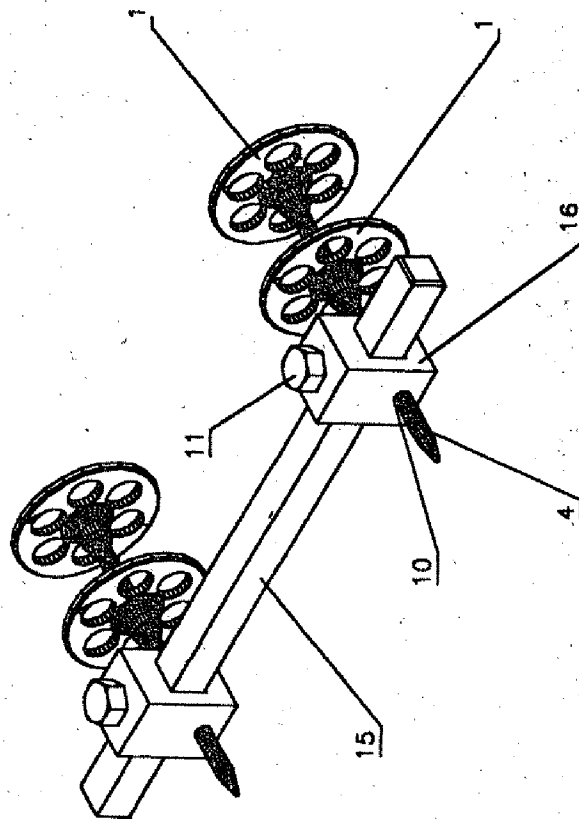


FIG. 3

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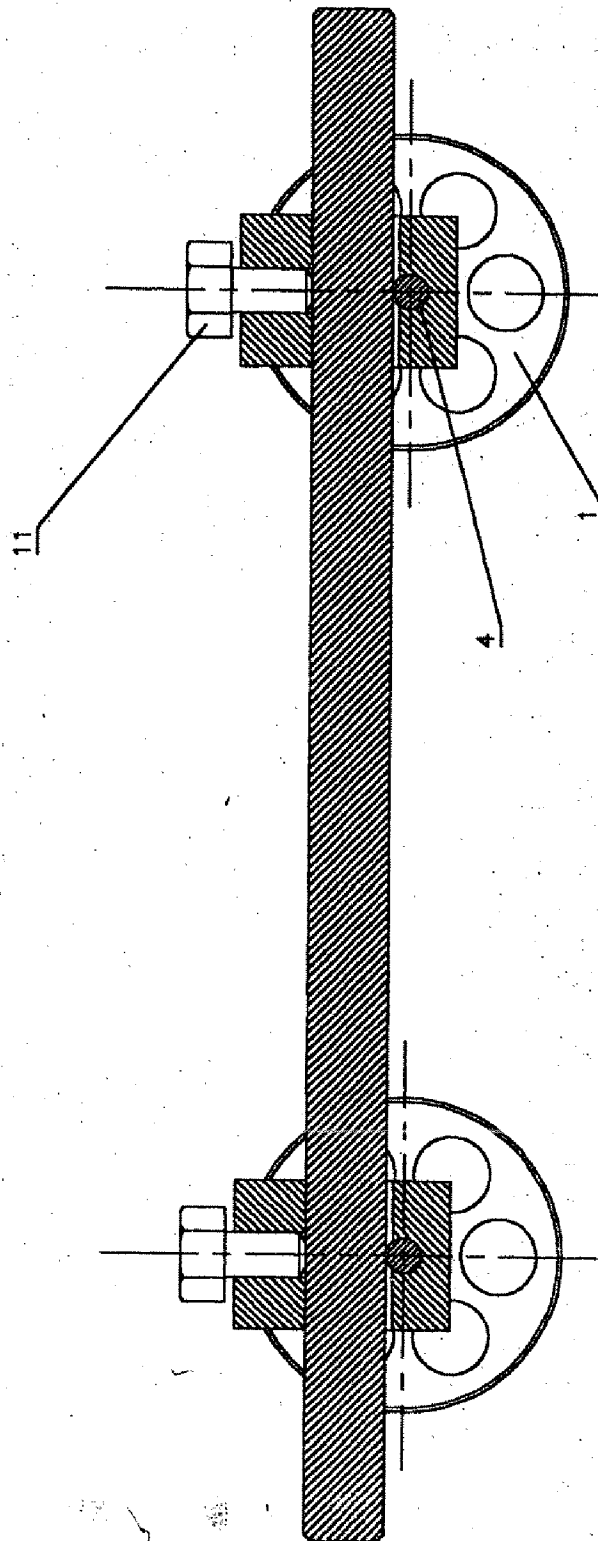


FIG. 4

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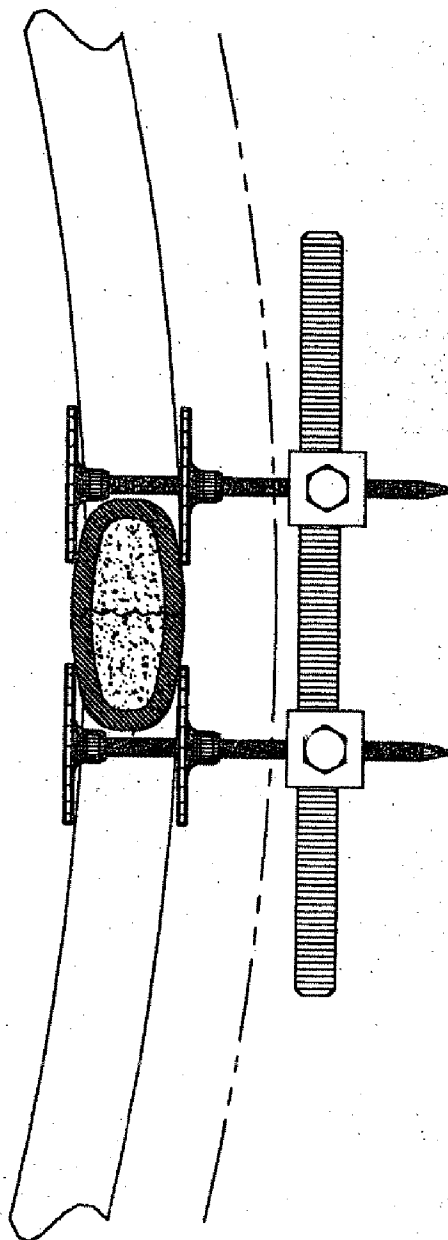


FIG. 6